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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,050	12/31/2001	Gregory Collier	12785	2282

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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,050	COLLIER ET AL.	
	Examiner	Art Unit	
	Christine Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-89* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-5 and 51-54, drawn to polynucleotides of SEQ ID NO:1 that encode the polypeptide of SEQ ID NO:2, classified in class 536, subclass 23.4.

II. Claims 6-9 and 55-58, drawn to polynucleotides of SEQ ID NO:3 that encode the polypeptide of SEQ ID NO:4, classified in class 536, subclass 23.4.

III. Claims 10-13, 18-20, 59-62, and 67-69, drawn to polynucleotides of SEQ ID NOs:5 and 9 that encode the polypeptide of SEQ ID NO:6, classified in class 536, subclass 23.4.

IV. Claims 14-17 and 63-66, drawn to polynucleotides of SEQ ID NO:7 that encode the polypeptide of SEQ ID NO:8, classified in class 536, subclass 23.4.

V. Claims 22-24, 35-36, 71-73, and 84-85, drawn to polypeptides of SEQ ID NO:2, classified in class 530, subclass 350.

VI. Claims 25-27, 35-36, 74-76, and 84-85, drawn to polypeptides of SEQ ID NO:4, classified in class 530, subclass 350.

VII. Claim28-30, 34-36, 77-79, and 84-85, drawn to polypeptides of SEQ ID NO:6, classified in class 530, subclass 350.

VIII. Claims 31-33, 35-36, and 80-85, drawn to polypeptides of SEQ ID NO:8, classified in class 530, subclass 350.

IX. Claim 37, drawn to methods of *modulating expression* of B38, B55, and/or B60 with an effective amount of *an agent*, classification dependent upon agent structure.

X. Claim 38, drawn to methods of *modulating activity* of B38, B55, and/or B60 with an effective amount of *an agent*, classification dependent upon agent structure.

XI. Claim 39, drawn to methods of treating a mammal by administering an agent that modulates the expression or activity of B38, B55, and/or B60, classification dependent upon agent structure.

XII. Claim 40, drawn to methods of treating a mammal by administering a protein, classified in class 514, subclass 2.

XIII. Claim 41, drawn to pharmaceutical compositions comprising B38, B55, and/or B60 or an agent capable of modulating B38, B55, and/or B60, classified in class 530, subclass 387.1.

XIV. Claim 42, 44-45, and 87-89, drawn to antibodies to a polypeptide, classified in class 530, subclass 387.1.

XV. Claim 43, drawn to antibodies to a nucleic acid, classified in class 530, subclass 388.21.

XVI. Claim 46, drawn to methods of detecting B38, B5 and/or B60 in a biological sample using a protein-specific antibody, classified in class 435, subclass 7.21.

XVII. Claim 47, drawn to methods of detecting B38, B5 and/or B60 in a biological sample using a nucleic acid-specific antibody, classified in class 435, subclass 6.

XVIII. Claims 48-49, drawn to methods of diagnosing and monitoring a disease comprising screening for B38, B55 and/or B60 in a biological sample, classification dependent upon compound structure.

XIX. Claim 86, drawn to a method of treating a mammal comprising administering a nucleic acid, classified in class 514, subclass 44.

Claims 1 and 50 link(s) inventions I-IV and XIX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 2-20, 37, 39, 41, 43, 47, 48, 49, 51-69, and 86. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 21 and 70 link(s) inventions V-XVIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 22-36, 38, 39, 40, 41, 42, 44-45, 46, 48, 49, 71-85, and 87-89. Upon the allowance of the linking claim(s), the

restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I, II, III, IV, V, VI, VII, VIII, XIII, XIV, XV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

The polynucleotide of Invention I can be prepared by processes which are materially different from the polynucleotide of Invention II, the polynucleotide of Invention III, the polynucleotide of Invention IV, the polypeptide of Invention V, the polypeptide of Invention VI, the polypeptide of Invention VII, the polypeptide of Invention VIII, the pharmaceutical composition of Invention XIII, the anti-polypeptide antibody of Invention XIV, and the anti-

polynucleotide antibody of Invention XV, such as by chemical synthesis or by isolation and purification from natural sources.

The polynucleotide of Invention II can be prepared by processes which are materially different from the polynucleotide of Invention I, the polynucleotide of Invention III, the polynucleotide of Invention IV, the polypeptide of Invention V, the polypeptide of Invention VI, the polypeptide of Invention VII, the polypeptide of Invention VIII, the pharmaceutical composition of Invention XIII, the anti-polypeptide antibody of Invention XIV, and the anti-polynucleotide antibody of Invention XV, such as by chemical synthesis or by isolation and purification from natural sources.

The polynucleotide of Invention III can be prepared by processes which are materially different from the polynucleotide of Invention I, the polynucleotide of Invention II, the polynucleotide of Invention IV, the polypeptide of Invention V, the polypeptide of Invention VI, the polypeptide of Invention VII, the polypeptide of Invention VIII, the pharmaceutical composition of Invention XIII, the anti-polypeptide antibody of Invention XIV, and the anti-polynucleotide antibody of Invention XV, such as by chemical synthesis or by isolation and purification from natural sources.

The polynucleotide of Invention IV can be prepared by processes which are materially different from the polynucleotide of Invention I, the polynucleotide of Invention II, the polynucleotide of Invention III, the polypeptide of Invention V, the polypeptide of Invention VI, the polypeptide of Invention VII, the polypeptide of Invention VIII, the pharmaceutical composition of Invention XIII, the anti-polypeptide antibody of Invention XIV, and the anti-

polynucleotide antibody of Invention XV, such as by chemical synthesis or by isolation and purification from natural sources.

The polypeptide of Invention V can be prepared by processes which are materially different from the polynucleotide of Invention I, the polynucleotide of Invention II, the polynucleotide of Invention III, the polynucleotide of Invention IV, the polypeptide of Invention VI, the polypeptide of Invention VII, the polypeptide of Invention VIII, the pharmaceutical composition of Invention XIII, the anti-polypeptide antibody of Invention XIV, and the anti-polynucleotide antibody of Invention XV, such as by chemical synthesis or by isolation and purification from natural sources.

The polypeptide of Invention VI can be prepared by processes which are materially different from the polynucleotide of Invention I, the polynucleotide of Invention II, the polynucleotide of Invention III, the polynucleotide of Invention IV, the polypeptide of Invention V, the polypeptide of Invention VII, the polypeptide of Invention VIII, the pharmaceutical composition of Invention XIII, the anti-polypeptide antibody of Invention XIV, and the anti-polynucleotide antibody of Invention XV, such as by chemical synthesis or by isolation and purification from natural sources.

The polypeptide of Invention VII can be prepared by processes which are materially different from the polynucleotide of Invention I, the polynucleotide of Invention II, the polynucleotide of Invention III, the polynucleotide of Invention IV, the polypeptide of Invention V, the polypeptide of Invention VI, the polypeptide of Invention VIII, the pharmaceutical composition of Invention XIII, the anti-polypeptide antibody of Invention XIV, and the anti-

polynucleotide antibody of Invention XV, such as by chemical synthesis or by isolation and purification from natural sources.

The polypeptide of Invention VIII can be prepared by processes which are materially different from the polynucleotide of Invention I, the polynucleotide of Invention II, the polynucleotide of Invention III, the polynucleotide of Invention IV, the polypeptide of Invention V, the polypeptide of Invention VI, the polypeptide of Invention VII, the pharmaceutical composition of Invention XIII, the anti-polypeptide antibody of Invention XIV, and the anti-polynucleotide antibody of Invention XV, such as by chemical synthesis or by isolation and purification from natural sources.

The pharmaceutical composition of Invention XIII can be prepared by processes which are materially different from the polynucleotide of Invention I, the polynucleotide of Invention II, the polynucleotide of Invention III, the polynucleotide of Invention IV, the polypeptide of Invention V, the polypeptide of Invention VI, the polypeptide of Invention VII, the polypeptide of Invention VIII, the anti-polypeptide antibody of Invention XIV, and the anti-polynucleotide antibody of Invention XV, such as by chemical synthesis or by isolation and purification from natural sources.

The anti-polypeptide antibody of Invention XIV can be prepared by processes which are materially different from the polynucleotide of Invention I, the polynucleotide of Invention II, the polynucleotide of Invention III, the polynucleotide of Invention IV, the polypeptide of Invention V, the polypeptide of Invention VI, the polypeptide of Invention VII, the polypeptide of Invention VII , the pharmaceutical composition of Invention XIII, and the anti-polynucleotide

antibody of Invention XV, such as by chemical synthesis or by isolation and purification from natural sources.

The anti-polynucleotide antibody of Invention XV can be prepared by processes which are materially different from the polynucleotide of Invention I, the polynucleotide of Invention II, the polynucleotide of Invention III, the polynucleotide of Invention IV, the polypeptide of Invention V, the polypeptide of Invention VI, the polypeptide of Invention VII, the polypeptide of Invention VIII, the pharmaceutical composition of Invention XIII, and the anti-polypeptide antibody of Invention XIV, such as by chemical synthesis or by isolation and purification from natural sources.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions IX, X, XI, XII, XVI, XVII, XVIII, and XIX are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention IX requires search and consideration of determining modulating expression, which is not required by any of the other Inventions. Invention X requires search and consideration of modulating activity, which is not required by any of the other Inventions. Invention XI requires search and consideration of treating a mammal using an unspecified agent, which is not required by any of the other Inventions. Invention XII requires search and consideration of treating a mammal using a protein, which is not required by any of the other Inventions. Invention XVI requires search and consideration of detection using a protein-specific antibody, which is not

required by any of the other Inventions. Invention XVII requires search and consideration of detection using a polynucleotide-specific antibody, which is not required by any of the other Inventions. Invention XVIII requires search and consideration of diagnosing and monitoring a disease, which is not required by any of the other Inventions. Invention XIX requires search and consideration of treating a mammal comprising administering a nucleic acid, which is not required by any of the other Inventions.

Inventions I-IV and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Inventions I-IV can be used in a materially different process such as diagnostic or biochemical assays.

Inventions V-VIII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Inventions V-VIII can be used in a materially different process such as diagnostic or biochemical assays.

Inventions XIV and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the anti-polypeptide antibody of Invention XIV can be used in a materially different process such as diagnostic or biochemical assays, or in the purification of the protein.

Inventions XV and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the anti-polynucleotide antibody of Invention XV can be used in a materially different process such as diagnostic or biochemical assays, or in a method of treatment.

Inventions I-IV and each of IX, X, XI, XII, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and each of IX, X, XI, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not

required, one for another. For example, the claimed methods of Inventions IX, X, XI, XVI, XVII, and XVIII do not recite the use or production of the polynucleotides of Inventions I-IV.

Inventions V-VIII and each of IX, X, XI, XVI, XVII, XVIII, and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and each of IX, X, XI, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IX, X, XI, XVI, XVII, XVIII, and XIX do not recite the use or production of the polypeptides of Inventions V-VIII.

Invention XIII and each of IX, X, XI, XII, XVI, XVII, XVIII, and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XIII and each of IX, X, XI, XVI, XVII, XVIII, and XIX are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IX, X, XI, XII, XVI, XVII, and XVIII do not recite the use or production of the agent of Invention XIII.

Invention XIV and each of IX, X, XI, XII, XVII, XVIII, and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XIV and each of IX, X, XI, XII, XVII, XVIII, and XIX are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IX, X, XI, XII, XVII, XVIII, and XIX do not recite the use or production of the anti-polypeptide antibody of Invention XIV.

Invention XV and each of IX, X, XI, XII, XVI, XVIII, and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XV and each of IX, X, XI, XII, XVI, XVIII, and XIX are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IX, X, XI, XII, XVI, XVIII, and XIX do not recite the use or production of the anti-polynucleotide antibody of Invention XV.

The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christine Saoud, Ph.D.** whose telephone number is **(571) 272-0891**. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
September 30, 2004

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